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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,911

08/18/2005

Ib Joergensen

17601.23a.1.1

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12/09/2009

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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

12/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,911	Applicant(s) JOERGENSEN ET AL.	
	Examiner VICTORIA P. CAMPBELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8,13 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-8,13 and 21-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the initial Office Action following the third Request for Continued Examination based on the 10/511911 application filed August 18, 2005. Claims 1, 4-8, 13, and 21-33 as amended are currently pending and considered below.

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification lacks antecedent basis for the terms "to provide substantial longitudinal separation between the proximal and distal portions" as now recited in claim 1 and "disposed end to end without overlapping" as now recited in claim 21.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention. The examiner notes that the limitations added to claims 1 and 21 indicated above lack enablement in applicant's specification.

4. Regarding claim 1, the limitation "to provide substantial longitudinal separation between the proximal and distal portions" is not supported by the specification as filed and as such, constitutes new matter.

5. Regarding claim 21 the limitation "disposed end to end" appears to have support in the drawings as filed. However, the applicant has indicated in Paragraph [0025] of the specification as filed October 20, 2004 that the "description of the embodiment of the present invention is provided for illustration only and not for the purpose of limiting the invention," thus the examiner has treated the figures and description as a non-limiting example. To this effect, the examiner notes that negative limitations, such as "without overlapping" as introduced in claim 21, *must* have basis in the original disclosure. Furthermore, the mere absence of a positive recitation is not basis for an exclusion, and the addition of this limitation to the claims is considered new matter.

MPEP § 2173.05(i)

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 4-8, 21, 22, 24, 25, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 4,960,410 to Pinchuk in view of USPGPub 2002/0072730 A1 to McGill et al.

Regarding the above claims, Pinchuk discloses a balloon catheter comprising a catheter shaft having a distal end (24), an inflatable balloon disposed on the distal end (12), a proximal end coupled to a connecting piece (30), a guiding wire lumen (22), and an inflation lumen (52). Pinchuk further discloses that the guiding wire lumen has coupled proximal (60) and distal (64) portions wherein the proximal portion is made of a

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more rigid metallic material and the distal portion is made of a less rigid plastic material (Col. 3, line 65-Col. 4, line 11). However, Pinchuk fails to explicitly teach or disclose that a transitional portion is provided with kink protection at least partially overlapping the proximal and distal portions. However, McGill et al teach a kink protection portion (205) which extends over both a proximal and distal portion, is connected to the proximal and distal portions of the pipe (connected has been given its broadest reasonable interpretation to mean joined or linked together, Merriam Webster Online Dictionary; as such permanent fixation is not required), wherein the kink protection prevents substantial longitudinal separation between the proximal and distal portions (although the proximal and distal portions are free to separate longitudinally, the kink protection portion substantially prevents them from coming apart completely, and therefore prevents substantial longitudinal separation). They further teach a second form a kink protection in the form of a metal coil (634), which the examiner believes could be placed inside or outside of the pipe. Furthermore, McGill et al teach a configuration wherein proximal and distal pipes meet end to end without overlapping at a transition, wherein a kink protection is provided about the transition at least partially overlapping the proximal and distal pipes (Figs. 16 and 17).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter of Pinchuk with the kink protection sleeve or metal coil of McGill et al, as well as the transition configuration, in order to provide increased stability in the catheter when navigating tortuous regions, as well as provide a

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more predictable change in stiffness of the catheter between the proximal region and the distal region, while maintaining an appropriate level of kink protection.

10. Claims 13, 23, 26, 27, 30, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk and McGill et al as applied to claims 4, 21, and 24 above, and further in view of USPN 5,951,494 to Wang et al.

Pinchuk and McGill et al disclose all of the limitations of claims 4, 21, and 24 as described above, but do not appear to explicitly disclose a lubricity enhancing coating on the inner surface of the guidewire lumen. However, Wang et al disclose coating the interior of a catheter lumen with a tube of TEFLON (Col. 16, lines 60-64), which can extend for any length of the tube. Pinchuk, McGill et al, and Wang et al are analogous art because they are from the same field of endeavor/problem solving area of catheters. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Pinchuk, McGill et al, and Wang et al before him or her to modify the interior lumen of Pinchuk and McGill et al to include the coating of Wang et al because doing so can help facilitate the introduction of a guidewire through the lumen (Wang et al, Col. 16, lines 62-64). Therefore, it would have been obvious to combine Pinchuk and McGill et al with Wang et al to obtain the invention in the instant claims.

11. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk, McGill et al, and Wang et al as applied to claim 27 above, and further in view of USPGPub 2003/0050600 A1 to Ressemann et al.

Ressemann et al further teach the limitation of plasma treating for increasing adherence, which the examiner asserts would be possible to do on either the interior of

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the catheter or the exterior of the plastic tubing. The examiner further asserts that this process renders the plastic tubing adherent, thereby making the outer layer adhesive. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the coating techniques of Ressemann et al with the catheter as stated above in order to ensure good adhesion of the friction-reducing interior polymeric layer.

12. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk and McGill et al as applied to claim 1 above, and further in view of USPN 6,596,217 B1 to Davis-Lemessy et al.

Davis-Lemessy et al teach the use of a nylon tube in the construction of a catheter (Col. 4, lines 15-40), which is not taught by either Pinchuk or McGill et al. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the nylon tube construction of Davis-Lemessy et al in order to be able to fusion bond with nylon balloons (Col. 4, lines 15-40).

Response to Arguments

13. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection. Regarding the new limitations presented in independent claims 1, 21, and 24, the examiner draws applicant's attention to the above rejections for the examiner's interpretation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763